DEC 1 3 2000

K002985

510(k) SUMMARY

Submitted by:	ICS MEDICAL CORPORATION 125 Commerce Drive Schaumburg, IL 60173-5329
Telephone:	(847)-534-2150
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Contact Person:	Delmar F. Bloem, President
Date Summary Prepared:	November 22, 2000
Trade Name of Device:	ICS Medical CHARTR®EP and CHARTR® OAE Systems.
Common Name:	Auditory Evoked Potential System and Otoacoustic Emissions Analyzer System.
Classification Name:	Auditory Evoked Potential System and Audiometer.
Description of Device:	Both the CHARTR®EP and CHARTR®OAE Systems are computer based. Two types of computers are involved: an IBM compatible tower system (MCU-90) and a portable computer referred to as "lunchbox" which is also IBM compatible. The first system measures evoked potentials following auditory stimuli while the OAE system detects and records otoacoustic emissions.
Intended Use:	The CHARTR®EP System is indicated for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway. The CHARTR®OAE System is indicated for use in testing the cochlear function of infants, children, and adults in a hospital, nursery, ENT clinic or audiology office. It measures otoacoustic emissions (OAE's) which allows the operator to get information about hearing sensitivity without a subjective response from the individual being tested. The presence of otoacoustic emissions indicates cochlear function.
Substantial Equivalence:	The CHARTR®EP System is substantially equivalent to the currently marketed CHARTR®EP. While the CHARTR®OAE is substantially equivalent to the Capella Devices marketed by Madsen Electronics located in Minnetonka, MN 55343.

Comparison of Similarities and Differences of Our New Medical Device to the Predicate Device:

	Windows CHARTR® EP K960097	CHARTR® EP the subject of this 510(k) Submission.
Indication for use. (EP System)	Indicated for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway.	Indicated for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway.
Operating System	Windows 95	Windows 98
Accessories	Identical for both units.	Identical for both units
40 Hz Test	No	Yes
P300 Test	No	Yes
Otoacoustic Emissions (OAE) Testing Capability	No	Yes, by installing OAE module using OAE software and associated probes and eartips.
Software	16 Bit	32 Bit
Computer System	MCU-80 (IBM Compatible Desktop)	MCU-90 (IBM Compatible Tower) and Portable (TFT active matrix screen) computer
Electrical Safety	Designed to comply with EN 60601-1 (UL 2601)	Designed to comply with EN 60601-1 (UL2601)
EMI Compatibility	Designed to comply with EN 60601-1-2	Designed to comply with EN 60601-1-2

With regard to the CHARTR® OAE System the Otoacoustic module and related software are virtually identical to those marketed by Madsen Electronics, Minnetonka, MN 55343 and cleared in their Capella 510(k)'s K983851 and K002200. The differences being that the ICS OAE modules draw their electrical power from the host computers (i.e. the MCU-90 and Portable). The software is identical with the exception that wherever Madsen and Capella are mentioned, these most likely will be substituted with corresponding ICS Medical nomenclature.

Electrical Safety: Both Systems are designed to meet EN 60601-1 standard for medical devices.

EMI Compatibility: Both Systems are designed to meet EN 60601-1-2 standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2000

Delmar F. Bloem
President
ICS Medical Corporation
125 Commerce Drive
Schaumburg, IL 60173

Re: K002985
Trade Name: ICS Medical CHARTR® EP and CHARTR® OAE Systems
Regulatory Class: II
Product Code: 84 GWJ, 77 EWO
Dated: September 22, 2000
Received: September 25, 2000

Dear Mr. Bloem:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K002985

Device Name: ICS Medical CHARTR® EP and CHARTR® OAE Systems

Indications for Use:

The CHARTR® EP System is indicated for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway.

CHARTR® OAE System is indicated for use in testing the cochlear function of infants, children, and adults in a hospital, nursery, ENT clinic or audiology office. It measures otoacoustic emissions (OAEs) which allows the operator to get information about hearing sensitivity without a subjective response from the individual being tested. The presence of otoacoustic emissions indicates cochlear function.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

James K. Kane, PhD

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002985

(Optional Format 3-10-98)

Prescription Use X
(Per 21 CFR 801.109)